# UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

D.P., an Infant, by His Mother and Natural Guardian L.P.,

**Plaintiffs** 

v.

JUUL LABS., INC.,

Defendant.

7:18-cv-05758 (CS)

# MEMORANDUM OF LAW IN OPPOSITION TO <u>DEFENDANT'S MOTION TO DISMISS</u>

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Plaintiff L.P. has sued Defendant JUUL Labs Inc. ("JUUL") on behalf of her 16-year old son D.P., alleging that JUUL's design and marketing of its e-cigarettes created an epidemic of teenage vaping, which in turn resulted in D.P. becoming addicted to nicotine and suffering other injuries. JUUL created this epidemic by designing its nicotine product to make it palatable for children, including through the use of sweet flavors, but with incredibly high levels of nicotine, and by marketing the product with a youth-oriented campaign that was strikingly reminiscent of the way tobacco companies hooked generations of children on cigarettes decades ago. Having secured a generation of captive customers, JUUL now insists that it had no intention to market its product to children or to anyone other than adult smokers, even though its design and marketing choices, along with its statements at the time, made no sense if adult smokers were truly its target audience.

JUUL now moves to dismiss the Amended Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6). JUUL's intellectual dishonesty and cynicism are front and center in this motion. The purpose of a 12(b)(6) motion, of course, is to determine whether the *plaintiff's* facts – the factual statements made in the complaint, accepted as true – make out the legal claims alleged. But JUUL's motion is not based on the facts that appear in the Amended Complaint. Instead, JUUL relies on JUUL's own "facts" – some of which it obtains through a gross distortion of the allegations of the Amended Complaint, and some of which it either pulls from thin air or takes from sources extraneous to the Amended Complaint.

The most striking example of this concerns JUUL's target consumers. The Amended Complaint makes detailed allegations, based on statements made by JUUL's founders and senior executives, that JUUL was not originally targeted to smokers but rather set out to to create a user community outside of current smokers by:

deliver[ing] solutions that refresh the magic and luxury of the tobacco category with a focus on recreating the "ritual and elegance

that smoking once exemplified," and thereby realize "a huge opportunity for products that speak directly to those consumers who aren't perfectly aligned with traditional tobacco products – people who want to enjoy tobacco but don't self-identify with—or don't necessarily want to be associated with—cigarettes.<sup>1</sup>

This allegation is a problem for JUUL because its whole defense in this case is based on its own claim that JUUL has always been intended for current smokers who want to switch to ecigarettes. But rather than directly address L.P.'s damaging allegations, JUUL simply ignores them and instead engages in a blatant and dishonest mischaracterization of other allegations in L.P.'s pleadings to elicit support for its argument. JUUL claims that paragraph 94 of the Amended Complaint "acknowledges that JUUL products are intended for smokers," and that paragraphs 2 and 40 of the original complaint, "conced[e] that the JUUL device is designed 'for adult smokers' and to 'wean addicts off cigarettes."

L.P.'s pleadings say no such thing. Paragraph 94 states only that JUUL has represented that it has designed its product for smokers, not that it actually had done so:

Defendants had a legal duty to design and market a safer-e-cigarette that would not attract users who were not previously addicted to nicotine. Defendants assumed that duty by announcing in their marketing materials that JUUL e-cigarettes were intended for smokers and Defendants intended to prevent children from using their products.<sup>4</sup>

The mischaracterizations of Paragraphs 2 and 40 of the original complaint are even more extreme. These paragraphs, in fact, state:

Though purportedly designed for adult smokers, Defendants' marketing of JUULe-cigarettes, much of which occurred on youth-heavy social media platforms, used imagery that appealed to youth.<sup>5</sup>

<sup>4</sup> Amended Complaint ¶ 94.

<sup>&</sup>lt;sup>1</sup> Amended Complaint and Demand for Jury Trial, Dkt. No. 50 ("Amended Complaint") ¶13.

<sup>&</sup>lt;sup>2</sup> Defendant's Memorandum of Law In Support of its Motion to Dismiss Plaintiff's Amended Complaint ("JUUL Mem.") 3.

<sup>&</sup>lt;sup>3</sup> JUUL Mem. 8.

<sup>&</sup>lt;sup>5</sup> Complaint and Demand for Jury Trial (Dkt. No. 1) ¶ 2.

The notion that JUUL e-cigarettes are or were intended to wean addicts off cigarettes is a farce of JUUL's creation.<sup>6</sup>

In addition to blatantly mischaracterizing L.P.'s pleadings, JUUL also simply invents its own "facts." A perfect example of this is JUUL's discussion of flavors: L.P. alleged that JUUL marketed its e-cigarettes in sweet, candy-like flavors such as mango, fruit medley and creme brulee and that these flavors

appealed to, and became wildly popular among underage users. A 2015 study, published months after JUUL's launch, found that 85.3 percent of current youth e-cigarette users had used a flavored e-cigarette in the past month and that 81.5 percent of current youth e-cigarette users said they used e-cigarettes "because they come in flavors I like."

Rather than accept L.P.'s facts on flavors as true and argue, or at least attempt to argue, that the facts do not make out the claims, JUUL instead contradicts L.P's facts with its own "fact" that does not appear anywhere in L.P.'s pleadings:

Adults—the only intended consumers of JUUL products—enjoy and find utility in flavors when transitioning away from cigarettes.<sup>8</sup>

JUUL engages in this tactic throughout its motion, presenting its "facts" concerning warning labels, nicotine formulations and palatability, among other things. While JUUL is free to introduce its "facts" at trial – if it can support them with relevant, admissible evidence – they are simply irrelevant at this stage of the litigation.

Finally, JUUL engages in what can be charitably described as artful legal argument but which can be better characterized as misleading and deceptive. The best example of this is JUUL's argument that L.P.'s failure to warn claim is preempted. JUUL cites a subsection of the Tobacco Control Act that preempts state and local regulation of tobacco labeling without

<sup>&</sup>lt;sup>6</sup> Id. at ¶ 40.

<sup>&</sup>lt;sup>7</sup> Amended Complaint ¶ 37.

<sup>&</sup>lt;sup>8</sup> JUUL Mem. at 13.

<sup>&</sup>lt;sup>9</sup> Id. at 18-20.

informing the Court of the very next subsection, which expressly excepts from preemption products liability cases like this one. JUUL then cites two cases that found claims to be preempted but does not inform the Court that those claims were consumer protection – not product liability – claims.

Based on the actual facts alleged in the Amended Complaint, along with the actual applicable law, L.P.'s products liability design defect, failure to warn, and negligence claims are clearly sufficient.

### **SUMMARY OF FACTUAL ALLEGATIONS**

The Amended Complaint makes detailed factual allegations, which are "assumed to be true" for the purposes of a 12(b)(6) motion. *Porrazzo v. Bumble Bee Foods, LLC*, 822 F. Supp. 2d 406, 409 (S.D.N.Y. 2011) (Seibel, J.); *see also Kugler v. Helfant*, 421 U.S. 117, 125, 95 S. Ct. 1524, 1531 (1975).

Contrary to JUUL's current claim that its sole intention has always been to provide a nicotine product to current adult cigarette smokers, from its inception JUUL aimed to create a new community of nicotine addicts, regardless of age. Indeed, JUUL's explicit intention was to recreate the cigarette, which one of JUUL's founders described as "the most successful consumer product of all time." By their own admission, JUUL's founders set out to "deliver solutions that refresh the magic and luxury of the tobacco category" with a focus on recreating the "ritual and elegance that smoking once exemplified," and thereby realize "a huge opportunity for products that speak directly to those consumers who aren't perfectly aligned with traditional tobacco products – people who want to enjoy tobacco but don't self-identify with—or don't necessarily

<sup>&</sup>lt;sup>10</sup> Amended Complaint ¶ 12.

<sup>&</sup>lt;sup>11</sup> Id. at ¶ 13.

<sup>&</sup>lt;sup>12</sup> Id.

want to be associated with—cigarettes."<sup>13</sup> To accomplish this goal, JUUL designed a product that was "elegant" and "would steer clear of the icons of the tobacco world like cigarettes and cigars."<sup>14</sup> This objective was realized with the JUUL, which looks nothing like a cigarette, and instead looks like a sleek, high-tech gadget.<sup>15</sup>

Relying heavily on tobacco industry research, JUUL engineered the JUUL nicotine solution to manipulate pH to maximize the delivery of nicotine. <sup>16</sup> By combining nicotine and benzoic acid, JUUL was able to provide an "additional nicotine 'kick'" that would increase the addictive potential of its product but with increased palatability – decreased irritation to the throat and respiratory tract of users. Meanwhile, another e-cigarette maker, who was seeking to attract former smokers, recognized that it had to engineer its solution to recreate the irritation, otherwise known as the "throat hit" that smokers found familiar. <sup>18</sup>

JUUL pairs palatability with extremely high levels of nicotine – much higher than traditional cigarettes. JUUL's patented formulation – 4% solution of benzoic acid and nicotine salt – delivers 36% more nicotine than Marlboro cigarettes. <sup>19</sup> Indeed, JUULs contain so much nicotine that JUUL has to sell lower-nicotine versions of its product in Europe, as the European Union prohibits e-cigarettes with the nicotine content of JUULs sold in the United States. <sup>20</sup>

Until recently, JUUL packaging contained no warnings about nicotine. Although warnings were placed on the outer packaging in October 2018 (several months *after* the original Complaint was filed),<sup>21</sup> there are still no nicotine warnings on the JUUL device or pods

<sup>&</sup>lt;sup>13</sup> Id.

<sup>&</sup>lt;sup>14</sup> Id. at ¶ 17.

<sup>&</sup>lt;sup>15</sup> Id.

<sup>&</sup>lt;sup>16</sup> Amended Complaint ¶ 27.

 $<sup>^{17}</sup>$  Id. at ¶ 23.

<sup>&</sup>lt;sup>18</sup> Id. at ¶ 27.

<sup>&</sup>lt;sup>19</sup> Id. at ¶ 33.

<sup>&</sup>lt;sup>20</sup> Id.

 $<sup>^{21}</sup>$  Id. at ¶ 34.

themselves even though as JUUL well knew, many youth users never see the packaging.<sup>22</sup> As a result, according to two separate 2018 studies, a majority of youth JUUL users did not believe the JUUL product contained nicotine.<sup>23</sup>

JUUL also followed the Big Tobacco youth addiction playbook by centering its product around sweet flavors likely to appeal to youth including mango, "fruit medley," and "creme brulee." JUUL's flavored products appealed to, and became wildly popular among, underage users, who, according to multiple studies, exhibited a strong preference for flavored ecigarettes. <sup>25</sup>

JUUL also, by its own admission, copied Big Tobacco's marketing and advertising strategies, using imagery relating to attractiveness, stylishness, sex appeal, fun, belonging, relaxation, and sensory pleasure; (including taste), which had been instrumental in attracting young people to cigarettes.<sup>26</sup> JUUL's original "Vaporized" advertising campaign that launched the JUUL product used young, stylish models with youthful hairstyles and dress, photographed in ways that mimicked underage teenagers, highlighted themes of sexual attractiveness, thinness, independence, rebelliousness and being "cool."<sup>27</sup>

Only now, after the uproar caused by the epidemic of JUUL use in high schools and middle schools, has JUUL abruptly changed course, turning to an advertising campaign, based primarily in traditional media such as television, radio and print advertising, and directed at current adult smokers.<sup>28</sup> Clearly positioning JUUL as an alternative to cigarettes, this campaign

<sup>&</sup>lt;sup>22</sup> Amended Complaint ¶ 34.

<sup>&</sup>lt;sup>23</sup> Id.

 $<sup>^{24}</sup>$  Id. at ¶ 36.

 $<sup>^{25}</sup>$  Id. at ¶ 37.

 $<sup>^{26}</sup>$  Id. at ¶ 45.

 $<sup>^{27}</sup>$  Id. at ¶ 46.

<sup>&</sup>lt;sup>28</sup> Amended Complaint ¶ 52.

lacks any hip, fun or cool imagery, and instead features middle-aged people explicitly identified as current smokers speaking seriously about the benefits of switching from cigarettes to JUUL.<sup>29</sup>

The damage, however, had already been done, with JUUL becoming so pervasive in high schools and middle schools that the United States Food and Drug Administration has characterized the situation as having reached "epidemic proportions." JUUL's awareness that the epidemic had happened, and its earlier realization that there was a significant risk that the epidemic could happen, were made clear in an August 2018 article in the New York *Times*. In that article, a former senior manager at JUUL stated that, pre-launch, JUUL was "well aware" that JUUL could appeal to teenagers and that post-launch, JUUL "quickly realized that teenagers were, in fact, using [JUULs] because they posted images of themselves vaping JUULs on social media." <sup>31</sup>

The health effects of this epidemic are extreme. According to the United States Surgeon General, besides causing nicotine addiction itself, the nicotine in JUULs and other e-cigarettes negatively influences adolescent brain development, specifically impairing cognitive, attention, and memory processes and increasing the risk of anxiety disorders and depression.<sup>32</sup> Moreover, according to the Surgeon General, there is a "potential association [of e-cigarette use] with cardiovascular disease." Finally, the Surgeon General reported that nicotine use increases the risk the adolescent will use other unlawful drugs, and several studies have shown that e-cigarette users are more likely to start smoking.<sup>33</sup>

<sup>&</sup>lt;sup>29</sup> Id.

<sup>&</sup>lt;sup>30</sup> FDA News Release, September 18. 2018, available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620788.htm <sup>31</sup> Amended Complaint ¶ 57.

 $<sup>^{32}</sup>$  Id. at ¶ 55.

<sup>&</sup>lt;sup>33</sup> Id.

In September 2017, D.P. entered a high school where JUUL e-cigarettes were pervasive and D.P. was offered JUUL "hits" throughout the day. <sup>34</sup> D.P. tried a JUUL offered to him at school and quickly became heavily addicted to nicotine. <sup>35</sup> D.P., like many youth JUUL users, prefers sweet flavors. D.P's JUUL flavor of choice is mango. <sup>36</sup>

D.P's addiction to nicotine has caused him to be withdrawn, anxious, highly irritable and prone to angry outbursts. D.P. has also began to perform poorly at school. <sup>37</sup> Despite his parents' serious measures to prevent D.P. from JUULing, D.P. is unable to stop even though it subjects him to disciplinary measures at home and at school<sup>38</sup> and puts him at risk for serious health problems including increased susceptibility to anxiety, depression and other addictions, plus a lifetime of economic losses needed to sustain a nicotine addiction for the remainder of his life. <sup>39</sup>

# **D.P.'S CLAIMS ARE LEGALLY SUFFICIENT**

# I. THE LEGAL STANDARD FOR A 12(b)(6) MOTION TO DISMISS.

In deciding a motion to dismiss for legal insufficiency, a court must determine whether the complaint "contain[s] sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face'." *Porrazzo v. Bumble Bee Foods, LLC*, 822 F. Supp. 2d 406, 410 (S.D.N.Y. 2011) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662 (2009) and *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570, (2007). "Facial plausibility" means that the plaintiff has pled "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* "Detailed factual allegations" are not necessary so long as the complaint's factual allegations are more than "labels and conclusions" or a "formulaic recitation of the elements of a

 $<sup>^{34}</sup>$  Id. at ¶ 63.

 $<sup>^{35}</sup>$  Id. at ¶ 64.

 $<sup>^{36}</sup>$  Id. at ¶ 65.

<sup>&</sup>lt;sup>37</sup> Amended Complaint ¶ 66.

<sup>&</sup>lt;sup>38</sup> Id. at ¶ 68.

 $<sup>^{39}</sup>$  Id. at ¶ 69.

cause of action." The task for the court is "context-specific," requiring the court to utilize "its judicial experience and common sense" to determine that the factual contentions permit the court "to infer more than the mere possibility of misconduct." *Id*.

As this Court has noted, it is axiomatic that, when deciding a Rule 12(b)(6) motion, the Court's "review is limited to the facts as asserted within the four corners of the complaint, the documents attached to the complaint as exhibits, and any documents incorporated in the complaint by reference." *Rankel v. Town of Somers*, 999 F. Supp. 2d 527, 537 (S.D.N.Y. 2014), citing *McCarthy v. Dun & Bradstreet Corp.*, 482 F.3d 184, 191 (2d Cir. 2007) and *Faulkner v. Beer*, 463 F.3d 130, 134 (2d Cir. 2006). Only under "limited circumstances" may a court may consider documents outside of the complaint on a motion to dismiss. *See Weiss v. Inc. Vill. of Sag Harbor*, 762 F. Supp. 2d 560, 567 (E.D.N.Y. 2011) (court may consider "documents 'integral' to the complaint and relied upon in it . . . and [] facts of which judicial notice may be taken"). By submitting seven exhibits, none of which are referenced in the Amended Complaint, and inserting its own set of factual allegations that at times ignore and other times contradict the L.P.'s actual allegations, JUUL has gone well beyond the four corners of the Amended Complaint.

### II. D.P.'S CLAIMS ARE LEGALLY SUFFICIENT.

As this Court has recognized, under New York law, "[a] manufacturer who places a defective product on the market that causes injury may be liable for the ensuing injuries." *Porrazzo*, 822 F. Supp. 2d at 416-17 (citing *Liriano v. Hobart Corp.*, 92 N.Y.2d 232, 237 (1998)). This liability, which exists "regardless of privity, foreseeability or the exercise of due care," so long as the plaintiff establishes the defectiveness of the product based on "either a manufacturing flaw, improper design, or a failure to provide adequate warnings regarding the use of the product and that the defect was a substantial factor in bringing about the injury." *Id*.

Here, L.P., who has made detailed factual allegations concerning design defects, including nicotine formulation, use of flavors and youth-oriented marketing, which rendered the JUUL product likely to appeal to children, as well as a lack of adequate labeling, adequately alleges design defect, failure to warn, and negligence claims.

#### A. L.P. ADEQUATELY ALLEGES A DESIGN DEFECT CLAIM.

The elements of a design defect claim are that "(1) the product, as designed, posed a substantial likelihood of harm; (2) it was feasible to design the product in a safer manner; and (3) the defective design was a substantial factor in causing the plaintiff's injury." *Rupolo v. Oshkosh Truck Corp.*, 749 F. Supp. 2d 31, 42 (E.D.N.Y. 2010).

L.P adequately alleges these elements. The Amended Complaint alleges that the JUUL product, as designed and marketed, poses a substantial likelihood of harm–namely an epidemic of youth nicotine addiction. 40 It alleges, among other things, that it was feasible to design and market the product in a manner that would have been safer–namely designing the product without sweet flavors; without excessive amounts of nicotine; without a nicotine formulation that makes JUUL extremely palatable to non-smokers (and, by eliminating the "throat hit," less appealing to smokers); and without marketing JUUL in a youth-oriented campaign that emphasized its coolness, sexiness and youthful appeal. 41 Finally, L.P. alleges that JUUL's design and marketing choices created a youth e-cigarette epidemic at high schools and middle schools across the country, including at the high school her son attended, and that, as a result, her son D.P. became addicted to JUUL's mango-flavored e-cigarettes. 42

JUUL attacks the sufficiency of the design defect claim in a number of non-meritorious ways: (1) that even though L.P.'s claim specifically focuses on JUUL's nicotine formulation and

<sup>&</sup>lt;sup>40</sup> Amended Complaint ¶ 2.

<sup>&</sup>lt;sup>41</sup> Id. at ¶ 44.

<sup>&</sup>lt;sup>42</sup> Id. at  $\P$  82.

how that formulation specifically led to the youth JUULing epidemic, JUUL contends that L.P. improperly seeks to hold JUUL responsible for the mere fact that JUULs contain nicotine and that as such L.P is impermissibly seeking to impose liability on the entire category of ecigarettes: (2) that even though JUUL does not claim the design defect claim is preempted, this Court should nonetheless decline to consider it and defer to potential FDA or legislative action that would not and could not compensate L.P and D.P. for their damages; (3) that even though the vast majority of youths who started JUULing, presumably including D.P., was not aware that JUULs contained nicotine, JUUL cannot be liable for causing D.P.'s nicotine addiction because the danger of becoming addicted to nicotine as a result of JUUL use is an obvious risk; (4) that even though L.P. lays out in the Amended Complaint several specific ways that JUUL could have designed a safer e-cigarette that would not appeal to children, L.P. has not alleged a feasible alternative design; and (5) even though it was completely foreseeable based on JUUL's conduct that minors would use JUUL, JUUL escapes liability because D.P. started JUUL use when he was 15 years old. None of these arguments have any merit.

1. L.P. Does Not Base Her Design Defect Claim On The Mere Presence of Nicotine and Does Not Seek To Impose Liability On A Whole Class of Products.

JUUL first mischaracterizes L.P.'s design defect claim by stating that L.P. improperly seeks to hold JUUL responsible for the fact that JUUL's contain nicotine "but delivering nicotine is precisely what JUUL products are supposed to do." JUUL pairs this mischaracterization with another – that by claiming that JUUL's product is defective because it contains nicotine, L.P. is making an impermissible "broad challenge to a class of products." L.P.

L.P's allegation is not that JUULs contain nicotine but rather that JUULs contain *excessive* amounts of nicotine and nicotine specifically formulated to be more palatable and

<sup>&</sup>lt;sup>43</sup> JUUL Mem. at 8.

<sup>&</sup>lt;sup>44</sup> Id. at 9.

avoid the throat hit smokers associate with cigarettes, which enables heavy use by young people not accustomed to cigarettes. Moreover, L.P. does not claim that all e-cigarette products containing nicotine are defective and her claims would not be applicable to an e-cigarette manufacturer, unlike JUUL, which avoided this manipulation and the other specific steps JUUL took to make its product appealing to children.

JUUL also improperly attempts to introduce and rely on its own "facts." JUUL contends that its products cannot be defective because they are "designed for adult smokers who would like to switch to a nicotine delivery system that satisfies the user's craving for nicotine but does not contain many of the harmful substances commonly found in traditional combustible cigarettes."<sup>45</sup> Similarly JUUL states that that "JUUL products contain nicotine sufficient to satisfy an adult smoker's desire for nicotine."<sup>46</sup> These factual allegations are, of course, not contained in the Amended Complaint. Indeed, the Amended Complaint says the exact opposite: that JUUL was designed for "consumers who aren't perfectly aligned with traditional tobacco products"<sup>47</sup> and that JUUL designed a product, with sweet flavors, slick design and nicotine formulated to avoid the "throat hit" that smokers have come to appreciate, that was at least as likely, if not more so, to appeal to young non-smokers than current adult smokers.<sup>48</sup> With respect to nicotine content, the Amended Complaint alleges that JUULs contain significantly more nicotine than necessary to satisfy an adult smoker's craving for nicotine.<sup>49</sup>

Based on these "facts" of its own creation, JUUL insists that there can be no tort design defect liability for its conduct and, despite not contending that the design defect claim is preempted, JUUL requests that this court abdicate its responsibility to determine the extent of a

<sup>&</sup>lt;sup>45</sup> JUUL Mem 9.

<sup>&</sup>lt;sup>46</sup> Id. at 10.

<sup>&</sup>lt;sup>47</sup> Amended Complaint ¶ 13.

<sup>&</sup>lt;sup>48</sup> Id. at ¶ 30.

<sup>&</sup>lt;sup>49</sup> Id. at ¶ 33.

manufacturer's liability on this traditional tort claim and defer to the FDA for action that may never come, and in any event, would not compensate L.P. and D.P. for their injuries.<sup>50</sup>

The cases cited by JUUL do not support its argument and have no bearing on L.P's actual claim and the facts that she has properly alleged. In *Rose v. Brown & Williamson Tobacco Corp.*, 53 A.D.3d 80, (1st Dept. 2008), *aff'd sub nom. Adamo v. Brown & Williamson Tobacco Corp.*, 11 N.Y.3d 545 (2008), the adult smoker plaintiff, who had prevailed before a jury on a design defect claim (but then died during the pendency of the appeal), claimed that the cigarettes she smoked were defective because they could have had lower levels of tar and nicotine. The First Department dismissed the claim because the plaintiff had not introduced evidence to the jury that lower tar and nicotine products would have had the same appeal to the public as "regular cigarettes." *Rose*, 53 A.D.3d at 84. The Court of Appeals affirmed and noted that "[t]o hold . . . that every sale of regular cigarettes exposes the manufacturer to tort liability would amount to a judicial ban on the product. If regular cigarettes are to be banned, that should be done by legislative bodies, not by courts." *Adamo*, 11 N.Y.3d at 551.

Rose could not be farther afield. The plaintiff was an adult and there was no claim that that the defendants had designed or marketed the product in a way that would appeal to children. Moreover, even if the proof deficiency in Rose were relevant, the facts alleged in L.P.'s Amended Complaint would remedy it. Since L.P. alleges that JUULs contain more nicotine than typical cigarettes, it could certainly be inferred that JUULs contain more nicotine than necessary for the product to appeal to cigarette smokers and that a lower nicotine e-cigarette would have the same appeal to adult smokers as the high nicotine e-cigarettes JUUL manufactures and

<sup>&</sup>lt;sup>50</sup> As noted in a recent federal court decision, the FDA has been remarkably passive in the face of the vaping epidemic, delaying the required pre-market review for several years while a generation of children becomes addicted to nicotine. *American Academy of Pediatrics, et al.*, *v FDA, et al.*, 2019 U.S. Dist. Lexis 81652 (D. Md. May 15, 2019) (finding that the F.D.A. acted outside its statutory authority by not expeditiously regulating e-cigarettes.)

markets. L.P. is not seeking to impose liability on all e-cigarette manufacturers, just on one—JUUL—which has targeted children.

Other cases relied on by the Defendant are similarly misleading and irrelevant. In *Tuosto v. Philip Morris USA Inc.*, 2007 U.S. Dist. LEXIS 61669 (S.D.N.Y. Aug. 21, 2007), where the court dismissed the design defect claim because the plaintiff had failed to identify any specific design defect that could have been remedied in a safer product, is distinguishable in that L.P. has alleged specific ways, ranging from a nicotine formula designed to appeal to current smokers, to avoiding sweet flavors, to a marketing strategy that did not appeal to youth, that would have made the JUUL product less appealing to children. *Clinton v. Brown & Williamson Holdings, Inc.*, 498 F. Supp. 2d 639, 648 (S.D.N.Y. 2007), where the court dismissed the design defect claim because the plaintiff's theory "would impose state law tort liability on the manufacture and sale of virtually every cigarette now on the market" is inapposite in that L.P.'s claims leave room for the manufacture and distribution of e-cigarettes that do not appeal to children.

Meanwhile, courts that have considered claims that actually resemble the one made in this case have sustained them. *See, e.g., Grisham v. Philip Morris, Inc.*, 670 F. Supp. 2d 1014, 1040 (C.D. Cal. 2009) (denying summary judgment on design defect claim where there was evidence that defendant cigarette manufacturer could have designed safer cigarette by reducing the levels of certain chemicals); *Rogers v. R.J. Reynolds Tobacco Co.*, 557 N.E.2d 1045, 1055, (Ind. Ct. App. 1990) (denying summary judgment based on question of fact "concerning the allegations in the amended complaint that the products are defective because Defendants failed to expeditiously explore design alternatives which would make their products less addictive").

JUUL also contends that its product cannot be defective for reasons related to nicotine because "the addictive nature of nicotine has been well known for many years." There are

<sup>&</sup>lt;sup>51</sup> JUUL Mem. 12.

several things wrong with this argument. First, there is no support for using that argument when the claim is made on behalf of a child, for whom the danger may not have been obvious. Second, L.P. alleges that JUULs did not contain nicotine warnings until October 2018,<sup>52</sup> a year after D.P. began JUULing and became addicted to nicotine,<sup>53</sup> and that according to two separate 2018 studies, a majority of youth JUUL users did not believe the JUUL product contained nicotine.<sup>54</sup> Third, even if D.P. could be charged with knowledge that nicotine is addictive,<sup>55</sup> and that JUULs contain nicotine, it still would not have been obvious to D.P. that JUUL had engineered its nicotine formulation to contain higher amounts of nicotine than that found in a typical cigarette and in a formulation that would enable heavy use.

# 2. JUUL's Sweet Flavors Are Cognizable Design Defects.

With respect to L.P.'s allegation that JUUL's marketing of the product in sweet flavors constitutes a design defect in that it makes the product more appealing to children, as discussed above, JUUL again relies on its own "fact" – that "adults—the only intended consumers of JUUL products—enjoy and find utility in flavors when transitioning away from cigarettes." Although JUUL claims with respect to this "fact," "plaintiff cannot plausibly allege otherwise," L.P. does exactly that, alleging in the Amended Complaint that studies have shown that 81.5 percent of current youth e-cigarette users said they used e-cigarettes "because they come in flavors I like." 18

<sup>&</sup>lt;sup>52</sup> Amended Complaint ¶ 34.

<sup>&</sup>lt;sup>53</sup> Id. at ¶ 62-64.

<sup>&</sup>lt;sup>54</sup> Id. at ¶ 34.

<sup>&</sup>lt;sup>55</sup> To the extent the Court finds that the factual allegations concerning D.P. 's knowledge of nicotine, or other matters related to JUUL, are determinative, the Court should grant L.P. leave to amend to add these allegations. It should be noted that JUUL's pre-motion letter did not focus on alleged deficiencies relating to D.P.'s own knowledge and so L.P. did not have notice of them prior to the filing of the Amended Complaint.

<sup>&</sup>lt;sup>56</sup> JUUL Mem. 13.

<sup>&</sup>lt;sup>57</sup> Id.

<sup>&</sup>lt;sup>58</sup> Amended Complaint ¶ 37.

Similarly, JUUL combines a gross mischaracterization of L.P.'s claim with its introduction of new "facts" when it contends that its use of sweet flavors and engineering of the pH of the nicotine formulation to remove the "throat hit" smokers associate with smoking is not cognizable as a defect because "the law does not require that JLI make its products taste bad and kick like a mule such that no consumer would ever want to use them."<sup>59</sup>

L.P. has alleged facts that indicate that the engineering of the formulation to eliminate the throat hit, along with the flavors, made the product more appealing for children while not being consistent with JUUL's current stated purpose of manufacturing and selling a product to current smokers who want to switch to e-cigarettes. <sup>60</sup> The contention that restricting its product to tobacco flavor and maintaining a nicotine pH that would preserve the "throat hit" (as other e-cigarette manufacturers did) would "make its products taste bad and kick like a mule" does not appear in the Amended Complaint and is not a proper basis for JUUL's motion.

# 3. L.P. Has Alleged A Feasible Alternative Design.

In contending that L.P. has not established the feasibility of an alternative design, JUUL repeats essentially the same arguments, based on its own "facts." L.P. has not alleged or conceded that JUUL products are designed "for adult smokers" or to "wean addicts off cigarettes," or that JUULpods contained nicotine "approximately equivalent to about 1 pack of cigarettes." Instead, L.P. has alleged that JUUL designed its product for "consumers who aren't perfectly aligned with traditional tobacco products" and that JUULpods contained far more nicotine than combustible cigarettes.

<sup>&</sup>lt;sup>59</sup> Id. at ¶ 14.

<sup>&</sup>lt;sup>60</sup> Amended Complaint ¶ 71.

<sup>61</sup> JUUL Mem. 8.

<sup>&</sup>lt;sup>62</sup> JUJUL Mem. 17.

<sup>&</sup>lt;sup>63</sup> Amended Complaint ¶ 13,33.

Given L.P.'s actual allegations, a product with less nicotine or even no nicotine would certainly appeal to consumers "who aren't perfectly aligned with traditional tobacco products." Even assuming that JUUL was intended to appeal, at least in part, to current smokers, a JUULpod with less nicotine and which did not come in sweet flavors would still provide the same nicotine as a combustible cigarette, taste like one, and still appeal to current smokers. Similarly, given that L.P. specifically alleged that other e-cigarette manufacturers engineered the nicotine formulation to preserve the throat hit to appeal to current smokers, 65 certainly JUUL could have done the same to reduce JUUL's appeal to children.

# 4. JUUL Can Be Held Responsible For D.P.'s Foreseeable JUUL Use.

JUUL relies heavily on an argument that L.P. cannot state a claim because D.P. used the product as a minor. As an initial matter, JUUL again improperly bases its argument on its own "fact," that does not appear in the amended complaint, that JUUL explicitly restricts its product to adults:

the packaging for JUULpods warned that they were 'the alternative for adult smokers,' 'NOT FOR SALE TO MINORS. Keep away from children and pets[,]" and that "1 JUULpod contains – 0.7mL with 5% nicotine by weight //approximately equivalent to about 1 pack of cigarettes. <sup>66</sup>

But again, the Amended Complaint – the only appropriate source of facts in this context – alleges that nicotine warnings on JUUL labeling did not appear until a year after D.P. started JUULing.<sup>67</sup>

Regardless, New York courts have made clear that a company can still be held responsible for its use of products by minors, even where use of the product was restricted to

<sup>&</sup>lt;sup>64</sup> Id. at ¶ 13.

<sup>&</sup>lt;sup>65</sup> Id. at ¶ 31.

<sup>66</sup> JUUL Mem. 17.

<sup>&</sup>lt;sup>67</sup> Amended Complaint ¶ 34.

adults. In *Campbell v. BIC Corp.*, 154 Misc. 2d 976, 586 N.Y.S.2d 871 (Sup. Ct. 1992), the plaintiff sued on behalf of his minor child who was burned while playing with a lighter that lacked child-resistant features. The court noted that in New York "a manufacturer also has the duty to design its product so that it avoids an unreasonable risk of harm when it is being used for an unintended but foreseeable use." *Id.* at 978. Given that "lighters manufactured by defendant are commonly used and kept about the home," the court held that "it is reasonably foreseeable that children will have access to them and will try to use them ... [and] defendant did owe plaintiff a duty of care." *Id; see also Price v. BIC Corp.*, 142 N.H. 386, 702 A.2d 330, 333 (1997) (holding that a design defect claim can be brought "when the risk that children might misuse the product was open and obvious to the product's manufacturer and its intended users"); *Bartholic v. Scripto-Tokai Corp.*, 140 F. Supp. 2d 1098, 1116 (D. Colo. 2000) (collecting cases on liability despite unauthorized use by minors).

Here, L.P. has alleged that JUUL had access to tobacco industry research concerning the popularity of sweet flavors with youth, promoted the JUUL product with a youth-centered campaign patterned on the tobacco industry's youth-oriented advertisements, and based on the statement to the New York *Times* of one of its senior managers, that the company was both aware of the risk that JUUL could appeal to children and, later, that JUUL was aware that children were heavy users of the JUUL product.<sup>68</sup> Clearly this is sufficient to establish that it was foreseeable that minors would use JUULs and that JUUL cannot escape liability based on D.P.'s use of JUUL as a minor.

### B. L.P.'S FAILURE TO WARN CLAIM IS SUFFICIENT.

The elements of a failure to warn claim are (1) that a manufacturer has a duty to warn; (2) against dangers resulting from foreseeable uses about which it knew or should have known; and

<sup>&</sup>lt;sup>68</sup> Id. at ¶ 57.

(3) that failure to do so was the proximate cause of harm. *Colon v. BIC USA, Inc.*, 199 F. Supp. 2d 53, 84 (S.D.N.Y. 2001). L.P. adequately alleges these elements. JUUL clearly had a duty to warn of the foreseeable danger of nicotine addiction. Had JUUL properly warned of this danger, which should have included nicotine warnings on the devices themselves, it is likely that there would not been the same epidemic of JUUL use among children. In addition, it can be inferred that adequate warnings would have been prevented D.P. from becoming addicted to nicotine.<sup>69</sup>

JUUL contends, without any merit, that this claim is preempted, that L.P. has not alleged causation and that it had no duty to warn about the "open and obvious" danger of nicotine addiction.

# 1. The Failure To Warn Claim Is Not Preempted.

JUUL contends that L.P.'s failure to warn claim is preempted by virtue of one provision of the Family Smoking Prevention and Tobacco Control Act ("TCA"), 21 U.S.C. § 387p(a)(2)(A), which does prohibit a state or local government entity from imposing regulatory requirements on certain aspects of tobacco products that are different from the FDA's requirements. Remarkably, however, JUUL ignores subsection (b) of the same statute, a savings provision, which provides:

No provision of this chapter [21 U.S.C. §§ 387 et seq.] relating to a tobacco product shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

21 U.S.C. § 387p(b). Since L.P.'s failure to warn claim is clearly a product liability claim, it is not preempted by the TCA.

JUUL's references to *Colgate v. JUUL Labs*, Inc., 345 F. Supp. 3d 1178 (N.D. Cal. 2018) and *In re Fontem US, Inc. Consumer Class Action Litig.*, 2016 U.S. Dist. LEXIS 187853

<sup>&</sup>lt;sup>69</sup> See fn 18, *supra*.

<sup>&</sup>lt;sup>70</sup> JUUL Mem. at 22.

(C.D. Cal. Nov. 1, 2016) are similarly misleading. In *Colgate*, the court properly recognized that JUUL's preemption argument applied only to the plaintiffs' false advertising claim. 345 F. Supp. 3d at 1187 (noting "JUUL argues that plaintiffs' false advertising claim must be dismissed because it is expressly preempted by the FDCA as amended by the TCA"). The court then went on to find that the aspects of plaintiffs' false advertising claims that relate to labeling are preempted and dismisses those claims. *Id.* at 1188-1189. Had the court intended to dismiss the products liability failure to warn claims that plaintiffs had also brought, *Id.* at 1186 (including "Strict Liability—Failure to Warn" as among the claims alleged in the complaint), it would have had to discuss the savings provision at 21 U.S.C. § 387p(b). In *Fontem*, the only claims brought under were state consumer protection statutes. *See* 2016 U.S. Dist. LEXIS 187853 at \*15 (listing claims in complaint as violations of the consumer protection laws of California, Illinois and New York and fraudulent concealment under Illinois law).

JUUL cites no case that had held that a product liability failure to warn case is preempted by the TCA. Indeed, courts have recognized that the savings provision in §387(p)(b) affirmatively permits products liability claims, even of those claims would have the effect of a ban on all tobacco sales. *Berger v. Philip Morris USA, Inc.*, 185 F. Supp. 3d 1324, 1340 (M.D. Fla. 2016).

Accordingly, by virtue of the savings provision embodied in 21 U.S.C. § 387p(b), L.P.'s products liability failure to warn claim is not preempted.

### 2. L.P. Sufficiently Alleges The Failure To Warn Caused D.P.'s Injuries.

JUUL contends that L.P. cannot establish causation on the failure to warn claims because she does not allege that D.P. saw the labeling and that D.P. began JUUL use based on what JUUL characterizes as "peer pressure."

To establish causation, L.P. only was required to show that the failure to warn was a substantial factor in causing D.P.'s injuries. *Colon v. BIC USA, Inc.*, 199 F. Supp. 2d 53, 83 (S.D.N.Y. 2001).

L.P. specifically alleged that JUUL's warning regarding nicotine were inadequate insofar as there were no warnings on JUUL packaging about nicotine prior to October 2018 and that there were never nicotine warning on the devices themselves, which is significant in that JUUL knew or should have known that JUUL devices were frequently sold and shared among children out of the packaging.<sup>71</sup> It can be inferred from this allegation that had JUUL included warnings on the devices themselves, D.P. could have avoided use of the JUUL product and avoided the damages he suffered.<sup>72</sup>

Moreover, L.P. also alleged that as a result of JUUL's conduct, which included the failure to warn, JUUL use became endemic in middle schools and high schools across the United States including the high school D.P. began attending in 2017. The prevalence of JUUL use among children led to D.P.'s JUUL use. Accordingly, JUUL's inadequate warnings were a substantial factor in D.P.'s JUUL use.

Courts have recognized that causation is established in these circumstances. *See Cote v. R.J. Reynolds Tobacco Co.*, 909 F.3d 1094,1109 (11th Cir. 2018)(finding that where tobacco companies' conduct has contributed to, or even failed to ameliorate, the peer pressure that led to youth smoking, they can be held responsible for the plaintiff starting to smoke); *Cty of Summit v. Purdue Pharma L.P.*, 2018 U.S. Dist. LEXIS 213657, at \*68-70 (N.D. Ohio Dec. 19, 2018) (causation established where opioid manufacturers' wrongful conduct led to opioid epidemic, which in turn caused plaintiffs' injuries); *In Re Opioid Litigation*, 2018 N.Y. Misc. LEXIS 2428,

<sup>&</sup>lt;sup>71</sup> Amended Complaint at ¶ 34.

<sup>&</sup>lt;sup>72</sup> See fn 18, *supra*.

at \*77 (Sup. Ct. Suffolk Cty)(finding causation based on the allegations "that the opioid epidemic allegedly spawned in part by the manufacturer defendants' false advertising caused the plaintiffs to suffer extraordinary losses."). *Cf. In re Avandia Mktg. Sales Practices & Prods. Liab. Litig.*,, 2013 U.S. Dist. LEXIS 152726, at \*23 (E.D. Pa. Oct. 22, 2013)(finding causation established even where no "first-party reliance" in that misrepresentations directed to physicians resulted in insurers suffering damages)

Accordingly, L.P. sufficiently alleged causation on the failure to warn claim.

3. JUUL's "Awareness Of Risk" and "Open And Obvious Danger" Defenses Do Not Appear On The Face Of The Complaint, and Therefore Cannot Be The Basis For A 12(b)(6) Dismissal.

JUUL also contends that the failure to warn claim is not sufficient because D.P. was aware of the risk that JUUL use could cause nicotine addiction and that the risk was "open and obvious."<sup>73</sup>

A contention that the injured party was aware of the risk that the defendant should have been warned against or that the risk was open and obvious is an affirmative defense, *see Munoz v. City of N.Y.*, 2012 N.Y. Misc. LEXIS 3762, \*4-5 (Sup. Ct. N.Y. Cty); *Johnson v. Am. Standard, Inc.*, 43 Cal. 4th 56, 74 Cal. Rptr. 3d 108, 179 P.3d 905 (2008) (defense that "sophisticated users need not be warned about dangers of which they are already aware or should be aware" is affirmative defense). An affirmative defense may be the basis for a 12(b)(6) dismissal only where the defense "appears on the face of the complaint." *Pani v. Empire Blue Cross Blue Shield*, 152 F.3d 67, 74 (2d Cir. 1998). Here, L.P. has certainly not alleged that D.P. was aware of the risk of nicotine addiction. Moreover, far from alleging that it was "open and obvious" that JUULs contained nicotine and could cause nicotine addiction, the Amended

<sup>&</sup>lt;sup>73</sup> JUUL Mem. at 22.

Complaint alleges the opposite—that a majority of youths were not aware JUULs contained nicotine.<sup>74</sup>

None of the cases cited by JUUL remotely support JUUL's argument that the case should be dismissed because, D.P., a fifteen-year-old at the time of his first JUUL use, should have known better. In Frazer v. ITW Food Equip. Grp. LLC, No. 11-CV-9699 (CS), 2013 WL 6164486 at \*5, this Court granted summary judgment on the defense, after discovery, based on evidence that the adult kitchen worker who injured her finger in an automatic mixer knew that she was not supposed to place her hand in the mixing bowl until the machinery stopped moving. In Kerr v. Koemm, 557 F. Supp. 283, 288 (S.D.N.Y. 1983), the court granted summary judgment, again after discovery, based on the defense where the facts showed that the defendant tractor manufacturer should not be required to warn against the danger of a tractor driver having "his three-year-old child standing on the running board, hanging onto his shirt as they rode a bumpy path over orchard land." In DePasquale v. Morbark Indus., 221 A.D.2d 409, 409, 633 N.Y.S.2d 543, 544 (2d Dept. 1995), the Appellate Division reversed a jury verdict on a failure to warn claim where "[t]he danger of injury if one's leg were to come in contact with the feed wheels on the wood chipping machine was obvious."

#### C. L.P.'S NEGLIGENCE CLAIMS ARE SUFFICIENTLY PLED.

The elements of a negligence claim are "(1) a duty owed by the defendant to the plaintiff, (2) a breach thereof, and (3) injury proximately resulting therefrom." *Solomon v. City of NY*, 66 N.Y.2d 1026, 1027, 489 N.E.2d 1294, 499 N.Y.S.2d 392 (1985). As a seller of a nicotine product ostensibly intended for adults, JUUL owed a duty to minors to design and market the product in a way such that it would not appeal to children. JUUL breached that duty by designing and marketing the product in a way to make it particularly appealing to children. As a result of that

<sup>&</sup>lt;sup>74</sup> Amended Complaint ¶ 34.

breach, JUUL created an epidemic of youth JUUL use, which resulted in D.P. using JUUL and becoming addicted to nicotine.

In seeking dismissal of the negligence claim, JUUL recycles the arguments from the product liability section of its brief that L.P.'s claims are about JUUL containing any amount of nicotine, that the claims seek to outlaw an entire class of product, and the failure to allege an alternative design. These arguments should be rejected for the same reason as set forth above: the case is not based on JUUL containing nicotine but rather a JUUL-specific nicotine formulation and JUUL-specific flavors engineered to attract young users instead of adult smokers, and that a design without these features would have the same utility if one were to assume JUUL's actual objective was to appeal to adult smokers.

JUUL also recycles its argument that JUUL cannot be held responsible since D.P. used the product as a minor. But again, since L.P. alleges that since JUUL use by minors was a *foreseeable result of JUUL's negligent conduct*, which included use of sweet flavors, engineering the nicotine formulation to make it more palatable to young smokers, and a youth-oriented marketing campaign, the intervening acts of third parties do not necessarily preclude causation and these issues require determination by the fact finder. *See Derdiarian v. Felix Contractor Corp.*, 51 N.Y.2d 308, 315 (1980).

L.P. sufficiently alleges causation since the Amended Complaint alleges that JUUL's conduct created the epidemic of youth JUUL use which in turn led to D.P. trying and becoming addicted to JUULs. Moreover, contrary to JUUL's contention that its use of sweet flavors was irrelevant to D.P.'s JUUL use, the Amended Complaint contains the allegation that D.P. prefers JUULs mango flavor, from which it can be inferred that the availability of the mango flavor led to or contributed to D.P.'s JUUL use.

Finally, JUUL characterizes L.P.'s negligent marketing claim as one that has been viewed skeptically by New York courts. This is flatly untrue. In the case cited by JUUL, *Hamilton v. Beretta U.S.A. Corp.*, 96 N.Y.2d 222, 239 (2001), the skepticism of the court was not based on the claim of negligent marketing but rather the effort to hold firearms manufacturers responsible for shooting deaths. In contrast, outside the firearms context, negligent marketing claims have been permitted. *See In Re Opioid Litigation*, 2018 N.Y. Misc. LEXIS 2428, at \*96-97 (Sup. Ct. Suffolk Cty.). Moreover, L.P.'s negligence claim is not limited to the marketing but based both on the design and the marketing of the product, further distinguishing it from *Hamilton*.

# **CONCLUSION**

JUUL's motion to dismiss should be denied.

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New York, New York

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